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September 9, 1994

Dr. Harry J. Pettengill
Director, Office of International Health Studies
Department of Energy
Office of Health, EH-40
270 Corporate Center
Washington, DC 20585

Dear Dr. Pettengill,

Attached is a short description of our sampling plan which we realize we had inadvertently left out of our overall epidemiologic/statistical protocol. The inclusion of this plan is meant to detail how we were to sample the population. It should have appeared on page 28 at the end of the section on **Statistical Power and the Required Sample Size** (before the **Epidemiologic Questionnaire** discussion.

This addendum is meant to amplify on our intentions and also to better respond to reviewer's comment B.2.3. We have realized, since the submission of the revised protocol, that our response to that comment was not appropriate and have revised our position as described in the addendum.

We would appreciate it if you could forward this information to those who are reviewing our revision (copies are enclosed) and please accept our apology for this oversight.

Thank you for your consideration.

Very truly yours,

Basil V. Worgul, Ph.D.
Director, Eye Radiation and
Environmental Research Laboratory

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(hp090994)

Addendum to Protocol

"Ocular Radiation Effects in the Chernobyl Liquidators" (Revised, 9/1/94)

Sampling Plan

The availability of a comprehensive dosimetry registry of Ukrainian Liquidators, assembled by Dr. Likhtaryov of the Center for Radiation Medicine, provides the potential for an unbiased sampling methodology. Specifically, we will use random sampling within strata of gender and age (5-year strata) to achieve a sample that is frequency matched across the dose categories. Since the sampling will be based strictly on the dosimetry data (obtained in 1986-87), it will not be biased by cataract status, provided that the participation rate is high and nonselective. The research team will make extended efforts to achieve a high participation rate across the dose range to achieve this goal.

As we have described in the section on statistical power, because the limiting factor in the sampling is the number of high-dose subjects, all subjects with estimated eye doses over 70 cGy will be selected for the study, and a stratified random sample of those under 70 cGy will be selected to fill the desired quotas in the various dose categories (see Table 4, page 25).

Many of the subjects in the more intensive, high-dose, Scheimpflug study (which is being conducted and funded under another grant) will also be in this study, but (1) because they number only a few hundred they will constitute only a small fraction of the present study and will thus have little impact; and (2) they will be flagged so that analyses can be conducted with and without them to determine if they create any bias.

Of the 30,000 Ukrainian workers in the dosimetry registry, about 3,000 currently have had refined dosimetric estimates made for the eye. The remaining 27,000 have only preliminary eye dose estimates. We will sample based on the current best dose estimates as of when the sampling is performed. A high priority will be given to working up the refined dose estimates for those selected for the study so that refined dose estimates can be used for all subjects in the data analyses. Although this means that some persons selected for the study will have final doses rather different from the preliminary doses on which their selection was based, this should not introduce any bias into the study. It is not feasible to calculate refined dose estimates on all 30,000 before selecting subjects for the study.